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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,167	08/01/2003	Gert Kniewasser	8074-21 (P15955 SB/asc)	4593

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Frank Chau, Esq.
F. CHAU & ASSOCIATES, LLP
1900 Hempstead Turnpike
East Meadow, NY 11554

EXAMINER

BUNIN, ANDREW M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,167

Applicant(s)

KNIEWASSER, GERT

Examiner

Andrew M. Bunin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Henry Bennett
Supervisory Patent Examiner
Group 3700

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 02017388.6, filed on 2/08/02.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the medicament source, the second opening closed off by a closer means such as a lid or slide, and a stopper of attachment piece to be partially inserted into hollow body must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 75. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. In claim 13, it is unclear as to how the attachment piece is turned relative to the hollow body. Although this is stated in the specification (pg. 3, lines 19-23), it is not discussed in the specification or drawings how the attachment piece has a closure means with which to close second opening by turning it. As for claim 14, it is unclear as to how the defined axis lies substantially perpendicular to axis of gas flow and medicament flow. This detail is not further explained or shown in the specification or drawings.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 4, 9, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Moa et al (US 5193532). Moa et al. include a device with a hollow body 19A in which an overpressure can be built up; a first opening 12 provided in a first side wall of the hollow body and used for introduction of a respiratory gas flow 14 directed into the hollow body 19A and for removal of the exhaled respiratory gas flow as shown in figures 1 and 2. In addition, Moa et al. include an attachment piece 23 which can fit on the hollow body 19A in order to connect the hollow body 19A to a nosepiece and/or mouthpiece 24. Lastly, Moa et al. include a second opening 13 provided in a second

sidewall of the hollow body 19A and used for introduction of a medicament flow 16 directed into the hollow body 19A (Since the disclosure does not clearly define what a medicament flow is, the examiner is reading the supply of fresh gas of Moa et al. as a medicament flow).

6. As for claim 3, Moa et al. includes a device characterized in that the hollow body 19A basically has the shape of a hollow cylinder on whose one end surface the attachment piece 23 can be fitted and on whose circumferential surface the first and second openings (12,13) are provided. As shown in figure 1, the first and second openings (12,13) lie at approximately the same height, so that the respiratory gas flow 14 directed into the hollow body 19A and the medicament flow 16 directed into the hollow body 19A at least partially intersect in an area 10. In addition, Moa et al. has shown in figure 1, a device characterized in that the first and second openings (12,13) are arranged at an acute angle to one another on the circumferential surface. In the abstract, Moa et al. states "two branch-channels together forming an acute angle" (line 13).

7. As for claim 11, Moa et al. discloses an attachment piece 23 that has one or two passages 24, which correspond to corresponding respiratory gas passages of the nosepiece and/or mouthpiece.

8. Lastly, Moa et al. disclose one or two outwardly pointing pipe stubs 24 for introduction into nosepiece and/or mouthpiece are provided in passages of that attachment piece 23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5-8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moa et al. (US 5193532). As shown in figure 1, after drawing a straight line, it can be seen that the pipe extends slightly outward on the bottom portion. Therefore, it can be considered obvious that this pipe is inserted into the second opening 13 and protrudes into the inside of the hollow body 19A (See illustration fig. 1 below). As for claim 6, it can also be seen in the figure that the pipe protrudes so far into the inside of the hollow body 19A that it forms a break-up edge for the respiratory gas flow directed into the hollow body (See illustration fig. 1 below). As for claim 7, the device of Moa et al. has shown that the pipe connected between 20 and 13 is fully capable of being plugged as well as another pipe can be plugged into this pipe.

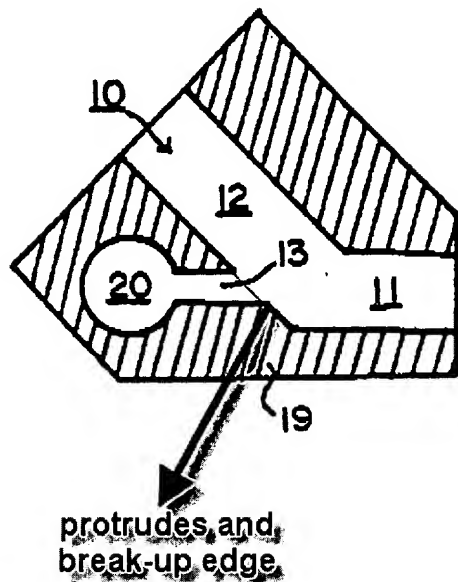


Figure 1: Fig. 3 of Moa et al.

10. For claim 8, it can be considered obvious to one of ordinary skill in the art to allow the second opening 13 to be capable of being closed off by a closure means, preferably a lid or slide in order to prevent dust and excess matter from entering the CPAP device.

11. For claim 10, it can be seen in the figure below that the attachment piece 23 consists of a stopper 1 (see fig. 2 below) which can be partially inserted into the hollow body 19A at the end surface as further shown in figure 6. A stopper can be considered anything preventing the attachment piece from moving further into the hollow body 19A. The angular sections of the attachment are partially inserted into hollow body 19A and prevent further movement into the hollow body 19A.

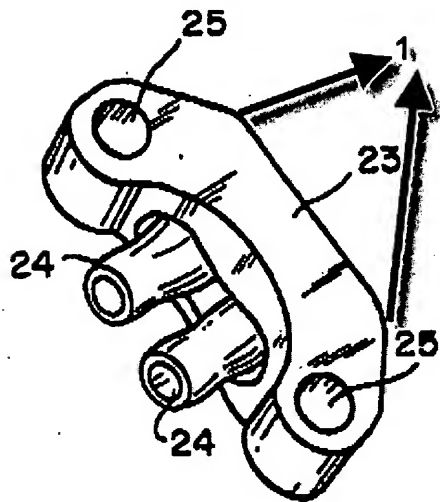


Figure 2: Fig. 5 of Moa et al.

12. Claim 2 and 15-18 are rejected under 35 U.S.C. 103(a) as being obvious over Moa et al. (US 5193532) in view of Werner et al. (WO 9924101)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR

1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Moa et al. discloses everything except a spacer to be fitted on the hollow body and on which a flow nozzle for directing the respiratory gas flow to the first opening can be arranged. However, Werner et al. teaches a spacer 40 to be fitted on the hollow body and on which a flow nozzle 50 for directing the respiratory gas flow to the first opening 12 can be arranged. In addition, Werner et al. teaches a spacer having a substantially annular or cup-shaped configuration as shown in the figure. Werner et al. also teaches a flow nozzle 50 to be guided through a hole in the side wall of the annular shape or cup shape and is oriented substantially perpendicular to the first opening. Lastly, Werner et al. continues to teach a flow nozzle 50 that projects by a predetermined length into the inside of the annular shape or inside of the cup shape. Therefore, it would have been obvious to one of ordinary skill in the art to combine the spacer as taught by Werner et al. to the device of Moa et al. in order to direct the airflow towards the first opening 12.

As for claim 18, Moa et al. discloses everything except a third opening for attachment of a pressure gauge. However, Werner et al. teaches a third opening for attachment of a pressure gauge on one sidewall of the hollow body 19A, preferably a sidewall different than the sidewall with the first opening 12. Therefore, it would have been obvious to one of ordinary skill in the art to combine a third opening to attach to a pressure gauge as taught by Werner et al. to the device of Moa et al. in order to measure the pressure in the hollow body.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 4098290, US 6807967, US 5975077, US 3319627, US 6125844, and US 5605148

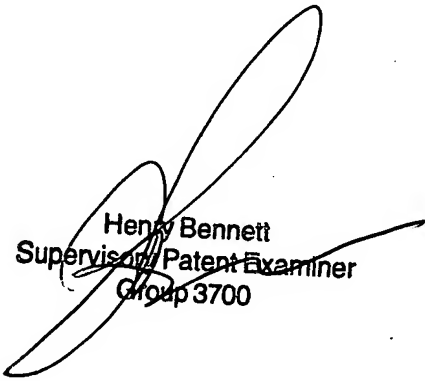
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Henry Bennett
Supervisor, Patent Examiner
Group 3700